Dietary supplement

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A prescribed **dietary supplement** supplies nutrients (usually vitamins or minerals) that are missing or not consumed in sufficient quantity in a person's diet.

Contents

United States

In the United States, a **dietary supplement** is defined under the Dietary Supplement Health and Education Act of 1994 as a product that meets each of the following criteria:

1. It is intended to supplement the diet and bears or contains one or more of the following dietary ingredients:
   - a vitamin,
   - a mineral,
   - an herb or other botanical (excluding tobacco),
   - an amino acid,
   - a dietary substance for use by man to supplement the diet by increasing the total daily intake (e.g., enzymes or tissues from organs or glands),
   - a concentrate, such as a meal replacement or energy bar, or
   - a metabolite, constituent, or extract.
2. It is intended for ingestion in pill, capsule, tablet, or liquid form.
3. It is not represented for use as a conventional food or as the sole item of a meal or diet.
4. It is labeled as a "dietary supplement".

The FDA regulates dietary supplements as foods, and not as drugs. The FDA does not pre-approve dietary supplements on their safety and efficacy, unlike drugs. In contrast, the FDA can only go after dietary supplement manufacturers after they have put unsafe products on the market. However, certain foods (such as infant formula and medical foods) are deemed special nutritionals because they are consumed by highly vulnerable populations and are thus regulated more strictly than the majority of dietary supplements.

The claims that a dietary supplement makes are essential to its classification. If a dietary supplement claims in any way to cure, mitigate, or treat a disease, it would be considered to be a unauthorized new drug and in violation of the applicable regulations and statutes. As the FDA states it:

> *No, a product sold as a dietary supplement and promoted on its label or in labeling as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved—and thus illegal--drug. To maintain the product's status as a dietary supplement, the label and labeling must be consistent with the provisions in the Dietary Supplement Health and Education Act (DSHEA) of 1994.*

The only claims that a dietary supplement is allowed to make are structure/function claims. These are broad claims that the product can support the structure or function of the body (e.g., "glucosamine helps support healthy

joints"). The FDA must be notified of these claims within 30 days of their first use, and there is a requirement that these claims be substantiated. Nevertheless, many critics claim that dietary supplements overstate their importance and their impact on overall health. Evidence of their benefits has yet to meet standard scientific criteria of credibility, based on large scale, double blind testing with statistically significant outcomes.

European Union

The **Food Supplements Directive**[1] requires that supplements be demonstrated to be safe, both in quantity and quality. Some vitamins are essential in small quantities but dangerous in large quantities. Some herbal remedies, notably St Johns Wort, are poisonous if taken with certain prescription drugs. Consequently, only those supplements that have been proven to be safe may be sold without prescription.

Legal challenge

The dietary supplements industry in Europe strongly opposed the Directive, having been accustomed to a high-profit, laissez-faire, approach in some countries. Consumer Groups have welcomed[2] the Directive, saying that it "will properly protect people who take supplements, ensuring that products are safe, that they contain forms of vitamins and minerals that offer some benefit, and that they are clearly labelled." (WHICH?, UK). The European Court of Justice ruled[3] on 12 July 2005 that the Directive is valid. However, it made clear that it must be possible for manufacturers to add materials to the list, that refusal must be on scientific grounds, and that there should be a right to appeal.

- *Note 1:* Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32002L0046:EN:HTML)
- *Note 2:* New European rules ensuring the safety of food supplements are good news for consumers. (http://www.which.co.uk/campaigns/food/nutrition/supplements.html)
- *Note 3:* The Court confirms the validity of the Community Directive on food supplements. (Press release) (http://www.curia.eu.int/en/actu/communiques/cp05/aff/cp050066en.pdf)

See also

- Codex Alimentarius

External links

- Dietary Supplement (http://www.cfsan.fda.gov/~dms/supplmnt.html) *Further information*
- Dietary Supplement Health and Education Act of 1994 (http://www.cfsan.fda.gov/~dms/dietsupp.html)
- Monitoring the Adverse Health Effects of Dietary Supplements (http://www.lsro.org/aers/frames_aers_reports.html) *Further information*
- What's in the Bottle? An Introduction to Dietary Supplements (NCCAM) (http://nccam.nih.gov/health/bottle/)
- Dietary Supplement Information on Food, Specialty and Digestive Supplements. (http://www.evitaminstore.com/store/listCategoriesAndProducts.asp?idCategory=110)
- BBC Health: Vitamins (http://www.bbc.co.uk/health/healthy_living/complementary_medicine/remedies_vitamins.shtml) on the BBC website. Note especially warnings [1] (http://news.bbc.co.uk/1/hi/health/4699041.stm) to pregnant women on Vitamin A (Retinol) and unspecified multivitamins.
- Supplement News (http://www.supplementnews.org/) - Supplement research and information.

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